DEC 2 3 2004

510 (k) Summary

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Submitters Information

Name:	Imaging Sciences International Inc.
Address:	1910 North Penn Road Hatfield PA, 19440
Phone Number:	215-997-5666
Fax Number:	215-997-5665
Person To Contact:	Edward J Marandola Vice President & General Manager
Date Of Summary:	November 15, 2004
Trade Name Of The Device:	SurgPLAN / PanPLAN
Common Or Usual Name:	X-Ray Software
Classification Name:	X-Ray, Software

Substantial Equivalence Claim: The Imaging Sciences International Inc. SurgPLAN / PanPLAN is substantially equivalent to the devices listed below:

Device	SimPlant
Manufacturer	Materialise/Columbia Scientific 810-x Cromwell Park Drive Glen Burnie, MD 21061
Device	CDRPan and CDR DICOM
Manufacturer	Schick Technologies Inc. 31-00 47th Avenue Long Island City, NY 11101

Description Of The Device: SurgPLAN / PanPLAN is a comprehensive software package that can scan films or certain solid state detectors, read DICOM images or DICOM volumetric data sets and display the images for the practitioner to perform analysis, measurements and surgical demonstrations for dental implants.

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Intended Use Of The Device: SurgPLAN / PanPLAN is a Software package that scans (scan film using optical scanner or Direct Digital Capture using Solid State Sensor) and stores images produced by Imaging Sciences International's (or other manufacturers') Tomographic, Panoramic and Cephlometric imaging machines. Additionally, the software has the ability to import DICOM images from volumetric data sets for visualization, analysis and reporting. The software allows the practitioner to perform surgical demonstrations for dental implant planning, cephlometric analysis, measurements and bone graft visualizations. The purpose of the software is to provide the doctor with a convenient method for visualization of these multiple imaging modalities, facilitates communication between multiple practitioners and to demonstrate treatment plan for the patient.

Comparison with Predicate devices: SurgPLAN / PanPLAN is a software package similar to the predicated devices. SurgPLAN / PanPLAN is a software package that combines functionality from both predicated devices in one simple program. Additionally it allows film-based users (through flatbed scanning) to have similar functions as digital users.

Conclusions: The performance testing of the Imaging Sciences International Inc. SurgPLAN / PanPLAN would indicate that the system is substantially equivalent to both predicated devices. The potential hazards (e.g. incorrect measurements or misdiagnosis) are controlled by the software development and validation system. SurgPLAN / PanPLAN software package complies with the requirements of 21 CFR 807.87 and does not pose any new safety risks or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2004

Mr. Edward J. Marandola
Vice President & General Manager
Imaging Sciences International, Inc.
1910 North Penn Road
HATFIELD PA 19440

Re: K041078
Trade/Device Name: SurgPLAN™ and PanPlan™
Regulatory Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 24, 2004
Received: November 29, 2004

Dear Mr. Marandola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041078

Device Name: SurgPLAN and PanPlan

Indications For Use:

SurgPLAN and PanPlan are Software packages that scan (scan film using optical scanner or Direct Digital Capture using Solid State Sensor) and store images produced by Imaging Sciences International's (or other manufacturer's) Tomographic, Panoramic and Cephlometric imaging machines. Additionally, the software has the ability to import DICOM images from volumetric data sets for visualization, analysis and reporting. The software allows the practitioner to perform surgical demonstrations for dental implant planning, cephlometric analysis, measurements and bone graft visualizations. The purpose of the software is to provide the doctor with a convenient method for visualization of these multiple imaging modalities and communication between multiple practitioners and to demonstrate treatment plan for the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041078

(Optional Format 1-2-96)